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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,604

06/27/2003

Kobi Richter

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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,604	<b>Applicant(s)</b> RICHTER, KOBI	
	<b>Examiner</b> SUZETTE J. GHERBI	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 4-30 and 32-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 31, 48-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/5/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's response dated 11/13/07 has been received in application serial number 10/607,604. The traversal is on the ground(s) that *"the restriction requirement can only be made if the process of making a product and the product are distinct"* and cites MPEP 806.05(i).

This is not found persuasive because the election/restriction dated 7/12/07 was based upon original presentation which stated:

Newly amended claims 37-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims were previously product claims. These claims have now been amended to be directed to a method for making a medical device.

Applicant's arguments are not commensurate to the previous action. Applicant did not previously "elect" any method claims and therefore the examiner did not provide any distinctions. Applicant's original claims were all product claims and applicant amendment shifted the invention over to method claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The claims being considered for further examination on the merits are claims 1-3, 31, 48 and 49. The requirement is still deemed proper and is therefore made **FINAL**.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 31, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon et al. (USPN 5,928,279) in view of McDonald et al. [5728150] or Pinchuk [5019090] and further in view of Masumoto et al. (USPN 4,614,221) or Miyazawa et al [4802776].

Shannon et al. discloses an implantable medical device in the form of a stent with all the elements of claims 1, 31, 37 and 41, but is silent to the alloy being amorphous and having a metalloid. See Figure 2 and column 6, lines 13-18 for a stent (14) being formed of wires (18), wherein the wires (18) are made from a cobalt metal alloy. While Shannon et al does not use a Statz type stent, such stents made from sheets of Elgiloy is taught by McDonald et al. Moreover, Miyazawa et al teaches forming amorphous sheet of elgiloy yielding improved physical properties similar to that as taught by Masumoto, et al. Whether the device is made from strands of wire or etched sheeting, it would have been obvious to one with ordinary skill in the art to use amorphous metal to enhance certain physical properties that may be desirable for the particular medical application. Masumoto et al. teaches using a cobalt or iron based alloy (Co-Si-B or Fe- Cr-P-B) to

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manufacture a thin metal wire according to a specific process in order for the wire to be of high quality, have a circular cross-section and an amorphous structure that has superior chemical, electromagnetic and physical properties. See column 3, lines 23-36 and 62-66, column 7, lines 3-8 and columns 7-8, lines 68-2. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the stent (14) of Shannon et al. by replacing the cobalt alloy wires (18) with the cobalt or iron based alloy (Co-Si-B or Fe-Cr-P-B) thin metal wires taught by Masumoto et al., which are of an amorphous alloy having a metalloid, in order for the wires to be of high quality, have circular cross-sections and an amorphous structure that has superior chemical, electromagnetic and physical properties.

Claims 2 and 3, see Figure 2 for the medical implant being in the form of a stent (14), which is structurally capable of being permanently or temporarily implanted.

Claim 31 is broader in scope than claim 1. (Note, the claim does not preclude wire products.)

Claim 48, see rejection to claim 1, supra, for the amorphous metal alloy

Claim 49, see rejection to claim 1, supra, for the amorphous metal alloy being an iron based alloy, and wherein the iron-based alloy contains Fe, Cr, B and P.

Claims 1-3, 31, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon et al. (USPN 5,928,279) in view of Masumoto et al. (USPN 4,614,221) as applied in the preceding paragraphs and Fariabi [5636641].

Fariabi teaches etching wires to remove surface oxides. To etch the wires of Shannon

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et al to remove surface oxides would have been obvious to one with ordinary skill in the art from the teachings of Fariabi.

### ***Response to Arguments***

Applicant's arguments filed 11/13/07 have been fully considered but they are not persuasive. Applicant traverses the election/restriction which has been addressed supra.

Applicant further contends the 103(a) rejection. Applicant states that Shannon does not teach or suggest a device that contains an etched amorphous metal alloy and provides a definition of the term "etched" which is not defined by the specification. It is further noted that applicants specification states on page 12 states that "The amorphous metal alloy stents of this invention may be made according to designs that **are well known in the art**". Nevertheless, the examiner had already pointed out that Shannon was silent to the alloy being amorphous and etching and provided a 103 rejection and teaching from Fariabi the teaches the etching wires to remove surface oxides. Pinchuk was also provided as a reference that taught etching of a hypodermic tube to provide slots. Applicant arguments state that Fariabi does not provide forming a pattern of fenestrations into the metal itself. This is a moot point as these limitations are not claimed. Claim 1 broadly states "an implantable medical device comprising an etched amorphous metal alloy formed into an implantable medical device..".

The forming of a stent or other medical devices by etching a sheet of metal is well known in the art as taught by Pinchuk ("5019090" reference to known Statz stents which states "*Another type of stent is known as a Statz stent, and it includes a hypodermic tube with longitudinal slots etched into its body*") and McDonald et al. The etched metallic sheet of McDonald is Elgiloy. While McDonald does not utilize amorphous metal in the sheet, Miyazawa et al teaches that enhanced properties, similar to that as taught by Masumoto, results in fabricating the Elgiloy sheet with amorphous metals. Contrary to applicant's arguments Masumoto and Miyazawa et al clearly teach improved physical properties that are attained in utilizing amorphous metal including high quality with superior chemical, electromagnetic and physical properties. Such improved properties would be equally applicable to devices in the medical field including implants which would enjoy the enhanced benefits of the metal alloy. There is no negative disclosure or teaching in either of Masumoto or Miyazawa et al that teaches away from the field of medicine or implantable devices. Examiner agrees with applicant's argument that Shannon is silent to the alloy being amorphous. However, this deficiency is overcome with the teachings of the secondary reference to Masumoto and Miyazawa et al. It is not essential that each secondary reference specifically teaches that the metal alloy wires could find medical application. What is critical in the application of the obvious rejection is the teachings of benefits to the material properties of an amorphous alloy. In this case, Masumoto and Miyazawa et al clearly teach improved properties are attained using the amorphous metals. Such improved properties would be equally applicable to devices in the medical field including implants

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which would enjoy the enhanced benefits of the metal alloy. It should be noted that Masumoto and Miyazawa et al teach that the metals could find applications in electric, electronic parts, electromagnetic parts, composite material and textile materials. Medical devices in the form of textiles (ie woven stent structures), electronic devices (ie. pacemakers, ablation catheters, artificial muscles, etc), electromagnetic (ie heart pump) and composite (reinforced bone plates, implantable hearing devices, etc) are all well known in the art and Masumoto does not make a distinction of the enjoyed benefits between medical and non-medical devices.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suzette J Gherbi/  
Primary Examiner, Art Unit 3738  
01 December 2008